



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2005-N-0101]

Agency Information Collection Activities; Proposed Collections; Comment Request;

Prescription Drug User Fee Program

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collections of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the *Federal Register* concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on information collection associated with FDA's Prescription Drug User Fee program.

DATES: Submit either electronic or written comments on the collection of information by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. The <https://www.regulations.gov> electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2005-N-0101 for "Agency Information Collection Activities; Proposed Collections; Comment Request; Prescription Drug User Fee Program." Received comments, those filed in a timely manner (see

ADDRESSES), will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240-402-7500.

- **Confidential Submissions**--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states “THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.” The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as “confidential.” Any information marked as “confidential” will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA’s posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.
- **Docket:** For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the “Search” box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240-402-7500.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-5733, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. “Collection of information” is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the *Federal Register* concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA’s functions, including whether the information will have practical utility; (2) the accuracy of FDA’s estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Prescription Drug User Fee Program

OMB Control Number 0910-0297--Revision

This information collection supports implementation of the Food and Drug Administration Prescription Drug User Fee (PDUFA) program. PDUFA was enacted in 1992 and authorizes FDA to collect fees from companies that produce certain human drug and

biological products. Under the prescription drug user fee provisions of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (sections 735 and 736 (21 U.S.C. 379g and 379h)), we have the authority to assess and collect user fees for certain new drug applications (NDAs) and new biologics license applications (BLAs). Under this authority, pharmaceutical companies pay a fee for certain new NDAs and BLAs submitted to FDA for review. We have established a PDUFA page on our website at <https://www.fda.gov/forindustry/userfees/prescriptiondruguserfee/> that includes resources and information regarding PDUFA topics at FDA.

Because the submission of user fees concurrently with applications is required, review of an application by FDA cannot begin until the fee is submitted. To assist respondents in this regard, we developed Form FDA 3397 entitled, “Prescription Drug User Fee Cover Sheet.” Associated instructions may be found on our website at <https://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm119184.htm>. The cover sheet (Form FDA 3397) need not be submitted for certain FDA-regulated products, e.g., generic drugs, and Whole Blood and Blood components for transfusion. The list of exempted products is included under the instructions to Form FDA 3397. Relatedly, sections 735 and 736 of the FD&C Act also provide for waiver, reduction, refund, and reconsideration requests. We developed the guidance document entitled “Guidance for Industry--User Fee Waivers, Reductions, and Refunds for Drug and Biological Products,” and Form FDA 3971 (Small Business Waivers and Refund Requests), which can be found on our website at <https://www.fda.gov/media/131797/download>.

We are revising the collection to include our current commitment goals, as set forth in the document “PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2018 Through 2022,” also found on our website at <https://www.fda.gov/media/99140/download>. PDUFA is currently authorized through September 30, 2022, with reauthorization activities currently underway. The commitment goals represent the product of FDA’s discussions with the regulated industry and public stakeholders, as mandated by Congress. FDA is committed to

meeting these goals and to continuous operational improvements associated with PDUFA implementation. The commitment goals provide for the development and issuance of topic-specific guidance. We maintain a searchable guidance database on our website at <https://www.fda.gov/regulatory-information/search-fda-guidance-document>. In publishing the respective notices of availability for each guidance document, we include an analysis under the PRA and invite public comment on the associated information collection recommendations. In addition, all Agency guidance documents are issued in accordance with our Good Guidance Practice regulations in 21 CFR 10.115, which provide for public comment at any time.

We estimate the burden of the information collection as follows:

Table 1.--Estimated Annual Reporting Burden ¹

Prescription Drug User Fee Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Sections 735 and 736 of the FD&C Act (PDUFA waivers, not including small business waivers)	112	1.68	189	17	3,213
Section 736(d)(1)(C) of the FD&C Act and Form FDA 3971 (small business waivers)	37	1	37	2	74
Reconsideration Requests	6	1.67	10	24	240
Appeal Requests	1	1	1	12	12
User Fee Cover Sheet Form FDA 3397	174	1	174	0.5 (30 minutes)	87
Total			411		3626

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

Based on a review of Agency records, we estimate that the number of initial waiver requests submitted annually (excluding small business waiver requests under section 736(d)(1)(C)) of the FD&C Act) will be 189, submitted by 112 different applicants; and that 37 respondents annually will each submit a small business waiver request. We have included in the burden estimate the time for preparation and submission of application fee waivers for small businesses, including completion of Form FDA 3971. Small businesses requesting a waiver must submit documentation to FDA, including the number of their employees, as well as

information that the application is the first human drug application, within the meaning of the FD&C Act, to be submitted to the Agency for approval.

We estimate receiving 10 requests for reconsideration annually (including small business waiver reconsiderations), and assume the average burden for preparing and submitting each request is 24 hours. In addition, we estimate receiving 1 request annually for appeal of user fee waiver determination, and assume the time needed to prepare an appeal is 12 hours. We have included in this estimate both the time needed to prepare the request for appeal to the Chief Scientist and User Fee Appeals Officer within the Office of the Commissioner, and the time needed to create and send a copy of the request for an appeal to the Director Division of User Fee Management within the Office of Management at FDA's Center for Drug Evaluation and Research.

We assume 87 hours of burden for completing and submitting Form FDA 3397 (Prescription Drug User Fee Coversheet) for submission of a new drug application or biologics license application.

The information collection reflects an overall increase since our last request for OMB review and approval. We attribute this to expected fluctuations in submissions to the Agency.

Dated: November 19, 2021.

Lauren K. Roth,

Associate Commissioner for Policy.

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